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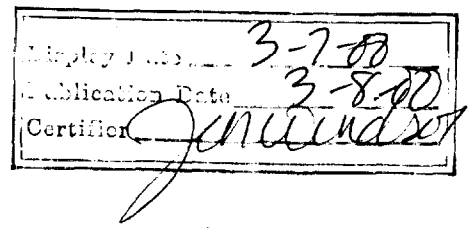

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–0109]

Draft Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices.'' This draft guidance is neither final nor is it in effect at this time. This guidance document would serve as a special control for the reclassification of fully automated short-term incubation cycle antimicrobial susceptibility devices from class III to class II.

DATES: Submit written comments concerning this guidance by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESS: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance to the Dockets Management Branch, (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852.

NAD 1

Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

On July 2, 1997, FDA received a petition from bioMerieux Vitek, Inc., requesting reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility devices from class III (premarket approval) to class II (special controls). Based on the petition, a meeting of the Microbiology Devices Panel (the Panel) was convened on February 13, 1998, to obtain the Panel's recommendation on the requested change in classification. The Panel unanimously recommended that fully automated short-term incubation cycle antimicrobial susceptibility devices be reclassified from class III to class II. This guidance document, which takes into consideration the Panel's recommendations and FDA's review experience, would be the special control for the reclassified device.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on fully automated short-term incubation cycle antimicrobial susceptibility devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate device must demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternative control that provides equivalent assurances of safety and effectiveness.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive a copy of the draft guidance entitled ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (631) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http:// www.fda.gov/cdrh. ''Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices'' will also be available at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, on or before [*insert date 90 days after date of publication in the* **Federal Register**], submit to Docket Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that

individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/9/00
February 9, 2000

Linda S. Kahan
Deputy Director for
Regulations Policy
Center for Devices and
Radiological Health

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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